

REMARKS

Applicant has amended claims 36, 37, 39-42 to resolve the § 112 issues raised in the previous action without acquiescence in the merits thereof. Claims 36 and 37 are clarified to recite the genus *Lactobacilli* (claim 36) and the specific strains (claim 37) as disclosed at page 1, line 11 and page 8, lines 21 – page 9, line 6, respectively.

The term “solid” is clarified by reciting “solid granular” as stated at page 12, lines 4-5 of the specification.

The species “germentum,” “salvaroes,” and “fermetti” of *Lactobacillus* are deleted.

Claims 39-42 are amended to recite “total mass” rather than “dry weight.”

These amendments resolve all outstanding issues under § 112, first and second paragraphs.

A Prime Facie Case of Obviousness Under § 103 Does Not Exist and the Combination of the Five References is Improper to Reject the Pending Claims.

Applicant notes that the issues under § 103 have been significantly clarified since the previous action in this case, and that no issues under § 102 remain.

The pending claims specify a dry admixture whose concentration and content limitations are not disclosed by the combination of references.

The Examiner’s characterization of the content of the references is not accurate. The Examiner cannot possibly maintain that Levy discloses *Lactobacillus* bacteria. The supposition that something is misnamed is completely baseless. The Levy reference discloses nothing more than the combination of *Bifido bifidum* (*Bifidus*) bacteria and lactic-acid yeast or Brewer’s yeast. One cannot

rename bacteria as yeast to meet the recited limitation. The claimed *Lactobacilli* bacteria are not taught by Levy and Levy does not disclose a protein concentrate as claimed. Moreover, the relative percent concentration of the yeast component in the Levy compositions is not within the claimed range. Levy never discloses less than 85% yeast. Thus, Levy cannot be the basis for a proper prima facie case under § 103 for either the bacteria, yeast concentrations or protein concentrate elements claimed.

As noted in the previous response, two well-established principles of the law of obviousness under 35 U.S.C. § 103 dictate that first, the cited prior art references must be considered “as a whole” and must suggest the desirability and thus the obviousness of making the combination. The Examiner’s position on the failure of the references to disclose a dry admixture of the components of the claimed compositions is contrary to law. Any combination of El-Megeed et al., Jolly (USP 4,107,334), and Friend necessarily yields a wet composition. Where three of five references combined in a § 103 rejection teach the same wet feature, over which the pending claims distinguish, one cannot simply choose to discard the wet feature to meet the dry admixture element of the present claims. To do so, one must fundamentally depart from the teachings of all of Friend, Jolly, and El-Megeed without any basis for doing so.

In addition to the failure of the references as a whole to teach the dry admixture, the specific concentrations and combinations are not fairly disclosed by the references alone or in combination. The Examiner proposes that one of ordinary skill in the art could have varied the proportions of the claimed elements from that disclosed in the prior art to arrive at the claimed percentages as part of an “optimization” of the components. This rationale cannot be used to render a claimed composition obvious unless the varied ingredients or parameters were recognized in the art as result-effective parameters. In re Antonie, 195 USPQ 6, 8 (CCPA 1977). The Examiner has cited no authority to

optimize the parameters in the manner proposed by the Examiner, e.g. reducing the yeast component of Levy, removing the water from El-Megeed, etc. An obviousness rejection cannot be based on the proposition that one of ordinary skill in the art would have been motivated to engage in an open-ended exercise to vary all possible parameters until one possible variation reaches an applicant's claimed invention. Such an exercise is merely an extension of the forbidden "obvious to try" standard, See In re O'Farrell, 7 USPQ2d 1673 (Fed. Cir. 1988).

Therefore, under the proper legal standard, one of ordinary skill in the art, possessing the teachings of Levy, Jolly, Prescott, El-Megeed et al. and Friend would not discard the teachings that require water in the formulations, nor substitute *Lactobacillus* for the *Bifidus bifidum* of Levy, nor add the protein concentrate as claimed, to provide the dry admixture of the claimed invention. To do so would require modifying the plain teaching of the references that disclose a wet composition, would require substituting the species of bacterium in Levy for those recited in the new claims, and would require adding a component to Levy that is nowhere stated therein. Moreover, the desirability of such a combination is not disclosed in any of the references. Such a reformulation would violate the rule explained in In re Gordon, 733 F.2d 900 (Fed. Cir. 1984) wherein the Federal Circuit held that a prior art reference may not be modified in a way that would render the prior art invention unsatisfactory for its intended purpose (See MPEP § 2143.01).

Clearly, the removal of water from a teaching of a formulation that is water-based would render the art unsatisfactory for the intended purpose. Further, with respect to the total mass percentages, a prior art reference describing a composition of matter with similar parameters will only render a claimed similar composition obvious by "optimization" of the parameters if the parameter was art recognized as result-effective. In Re Antonie 195 USPQ 6 (CCPA 1977) (See

MPEP § 2144.05, II. B.). None of the parameters recited in the claims is shown in the art to be successfully altered to achieve the result here.

Applicant notes the double patenting rejection over co-pending application 08/879,220. At an appropriate time, a terminal disclaimer will be filed if the claims as allowed in the present application remain coextensive with application 08/879,220.

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS:

Please amend claims 36-37, 39 – 42 as follows:

36. (Amended) A nutritional supplement composition comprising:
a sealed container containing a solid granular, dry admixture wherein said admixture is comprised of dried, viable [Lactobacilli] bacteria of genus Lactobacilli,
non-living, dried Brewer's or Baker's yeast in an amount comprising between about 2.5% and about 20% of the total mass of the composition, and
a protein concentrate selected from the group consisting of whey protein, soy protein, and animal protein concentrates.

37. (Amended) The composition of claim 36, wherein the genus *Lactobacilli* bacteria is selected from the group of [genera or species] consisting of strains *Lactobacillus acidophilus*, *Lactobacillus bulgaricus*, *Lactobacillus casei* [*Lactobacillus germentum*,] *Lactobacillus helveticus*, *Lactobacillus bifidus*, *Lactobacillus lactis*, *Lactobacillus delbrueckii*, *Lactobacillus thermophilus*, [*Lactobacillus fermenti*,] *Lactobacillus coryniformis*, *Lactobacillus curvatus*, *Lactobacillus buchneri*, *Lactobacillus fermentum*, *Lactobacillus viridescens*, *Lactobacillus amylovorus*, *Lactobacillus amylophilus*, *Lactobacillus pentosaceus*, [*Lactobacillus salivaro*es,] *Lactobacillus brevis*, *Lactobacillus leichmannii*, *Lactobacillus plantarum*, and *Lactobacillus cellobiosus*.

39. (Amended) The composition of claim 36, wherein the viable dried bacteria component comprises from about 0.25% to about 5.0% of the total mass [dry weight] of the composition.

40. (Amended) The composition of claim 36, wherein the non-living dried yeast component comprises from about 3.0% to about 12.5% of the total mass [dry weight] of the composition.

41. (Amended) The composition of claim 36, wherein the protein component comprises from about 50% to about 97% of the total mass [dry weight] of the composition.

42. (Amended) The composition of claim 36, wherein the protein component comprises from about 75% to about 96% of the total mass [dry weight] of the composition.